Draft Regulations laid before Parliament under section 47(3), (4) and (6)(a) of the Medicines and Medical Devices Act 2021 (c. 3) and paragraphs 8F(1) and (2)(c) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 (c. 16), for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2025 No.

MEDICAL DEVICES

FEES AND CHARGES

The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2025

Made - - - - ***

Coming into force in accordance with regulation 1(2)

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8C(1)(a) and (c) of, and paragraphs 1(1)(ab) and 7(2)(**a**) of Schedule 4 and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**b**), and sections 15(1), 16(1), 17(1)(a) and 43 of the Medicines and Medical Devices Act 2021(**c**).

The Secretary of State has carried out a public consultation in accordance with section 45(1) of the Medicines and Medical Devices Act 2021.

In accordance with section 15(2) to (4) of the Medicines and Medical Devices Act 2021, the Secretary of State's overarching objective in making these Regulations is safeguarding public health, and the Secretary of State has had regard to the matters specified in section 15(3) of that Act, and the Secretary of State considers that, where these Regulations may have an impact on the safety of medical devices, the benefits of making these Regulations outweigh the risks.

In accordance with section 47(3), (4) and (6)(a) of the Medicines and Medical Devices Act 2021 and paragraphs 8F(1) and (2)(c)(**d**) and 12(1) of Schedule 7 to the European Union (Withdrawal)

(**a**) The powers in paragraphs 1(1)(ab) and 7(2) of Schedule 4 to the European Union (Withdrawal) Act 2018 are exercisable by the "appropriate authority". See paragraph 2 of that Schedule, which defines "appropriate authority" for the purposes of paragraph 1 of that Schedule. See also paragraph 8 of that Schedule, which defines "appropriate authority" for the purposes of paragraph 7 of that Schedule.

(**b**) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act"). Section 8C was inserted by section 21 of the 2020 Act, and paragraph 1(1)(ab) of Schedule 4 by section 28 of the 2020 Act. Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act.

(**c**) 2021 c. 3. The Medicines and Medical Devices Act 2021 was amended by the Health and Care Act 2022 (c. 31).

(**d**) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.

Act 2018, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

The Treasury have consented to the making of these Regulations as required by paragraphs 3(1) and 10 of Schedule 4 to the European Union (Withdrawal) Act 2018.

PART 1

Preliminary

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2025.

(2) These Regulations come into force on the twenty-first day after the day on which they are made.

(3) Any amendment or omission made by these Regulations has the same extent and application as the provision amended or omitted, subject to paragraph (4).

(4) In Part 2—

(a) regulations 3, 5, 6 and 8 apply in relation to England and Wales and Scotland;

(b) regulations 4 and 7 apply in relation to Northern Ireland;

(c) regulations 11 and 12 extend and apply to England and Wales, Scotland and Northern Ireland.

PART 2

Amendment of the Medical Devices Regulations 2002

Amendment of the Medical Devices Regulations 2002

2. The Medical Devices Regulations 2002(**a**) are amended in accordance with regulations 3 to 12.

Amendment of regulation 53 in relation to England, Scotland and Wales

3. In regulation 53 (fees in connection with the registration of devices and changes to registration details)(**b**), for "£240" substitute "£261".

Amendment of regulation 53 in relation to Northern Ireland

4. In regulation 53 (fees in connection with the registration of devices and changes to registration details)(**c**), for "£240" substitute "£261".

(**a**) S.I. 2002/618; relevant amending instruments are 2003/1697, 2007/400, 2007/803, 2008/2936, 2010/557, 2012/1426, 2013/525, 2013/2327, 2017/207, 2019/791, 2020/1478, 2021/873, 2021/910, and 2023/377.
(**b**) Amended by S.I. 2019/791 and 2023/377.
(**c**) Amended by S.I. 2020/1478 and 2023/377.

Amendment of regulation 54 in relation to England, Scotland and Wales

5. In regulation 54 (fees payable in connection with the designation of approved bodies)(**a**)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£8,918" substitute "£10,335";

(ii) in sub-paragraph (b), for "£35,672" substitute "£41,337";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£12,571" substitute "£14,568";

(ii) in sub-paragraph (b), for "£18,212" substitute "£21,105";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£58,341" substitute "£67,606";

(ii) in sub-paragraph (b), for "£45,675" substitute "£52,929";

(iii) in sub-paragraph (c), for "£10,072" substitute "£11,672";

(d) in paragraph (3A)—

(i) in sub-paragraph (a)(i), for "£631" substitute "£732";

(ii) in sub-paragraph (a)(ii), for "£171" substitute "£198";

(e) in paragraph (3C)—

(i) in sub-paragraph (a), for "£35,672" substitute "£41,337";

(ii) in sub-paragraph (b), for "£58,341" substitute "£67,606";

(f) in paragraph (3D)—

(i) in sub-paragraph (a), for "£18,583" substitute "£21,535";

(ii) in sub-paragraph (b), for "£22,789" substitute "£26,408";

(g) in paragraph (3E), for "£1,297" substitute "£1,503";

(h) in paragraph (3F), for "£22,789" substitute "£26,408".

Amendment of regulation 55 in relation to England, Scotland and Wales

6. In regulation 55 (fees payable in connection with the designation etc. of conformity assessment bodies)(**b**)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£8,918" substitute "£10,335";

(ii) in sub-paragraph (b), for "£35,672" substitute "£41,337";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£12,571" substitute "£14,568";

(ii) in sub-paragraph (b), for "£18,212" substitute "£21,105";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£58,341" substitute "£67,606";

(ii) in sub-paragraphs (b) and (d), for "£10,072" substitute "£11,672";

(d) in paragraph (3A), for "£58,341" substitute "£67,606";

(e) in paragraph (3B), for "£10,072" substitute "£11,672";

(**a**) Relevant amending instruments are S.I. 2019/791 and 2023/377.
(**b**) Relevant amending instruments are S.I. 2007/803, 2019/791, and 2023/377.

(f) in paragraph (3D)—

(i) in sub-paragraph (a)(i), for "£631" substitute "£732";

(ii) in sub-paragraph (a)(ii), for "£171" substitute "£198".

Amendment of regulation 55 in relation to Northern Ireland

7. In regulation 55 (fees payable in connection with the designation etc. of conformity assessment bodies)(**a**)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£8,918" substitute "£10,335";

(ii) in sub-paragraph (b), for "£35,672" substitute "£41,337";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£12,571" substitute "£14,568";

(ii) in sub-paragraph (b), for "£18,212" substitute "£21,105";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£58,341" substitute "£67,606";

(ii) in sub-paragraphs (b) and (d), for "£10,072" substitute "£11,672";

(d) in paragraph (3A), for "£58,341" substitute "£67,606";

(e) in paragraph (3B), for "£10,072" substitute "£11,672";

(f) in paragraph (3D)—

(i) in sub-paragraph (a)(i), for "£631" substitute "£732";

(ii) in sub-paragraph (a)(ii), for "£171" substitute "£198".

Amendment of regulation 56 in relation to England, Scotland and Wales

8. In regulation 56 (fees payable in relation to clinical investigation notices)(**b**)—

(a) in paragraph (1)—

(i) in sub-paragraph (a)(i), for "£5,711" substitute "£11,701";

(ii) in sub-paragraph (a)(ii), for "£11,069" substitute "£22,678";

(iii) in sub-paragraph (b)(i), for "£7,472" substitute "£15,309";

(iv) in sub-paragraph (b)(ii), for "£15,627" substitute "£32,016";

(b) in paragraph (3A)—

(i) in sub-paragraph (a), for "£207" substitute "£226";

(ii) in sub-paragraph (b), for "£331" substitute "£361";

(c) in paragraph (3B)—

(i) in sub-paragraph (a), for "£906" substitute "£987";

(ii) in sub-paragraph (b), for "£782" substitute "£852".

Amendment of regulation 56C

9. In regulation 56C (fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device)(**c**)—

(**a**) Amended by S.I. 2020/1478 and 2023/377.
(**b**) Amended by S.I. 2019/791 and 2023/377.
(**c**) Inserted by S.I. 2023/377.

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£4,550" substitute "£4,953";

(ii) in sub-paragraph (b), for "£10,604" substitute "£11,543";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£900" substitute "£980";

(ii) in sub-paragraph (b), for "£2,451" substitute "£2,668";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£46,526" substitute "£50,644";

(ii) in sub-paragraph (b), for "£11,551" substitute "£12,574".

Omission of regulation 56D

10. Omit regulation 56D (fees payable in connection with pre-consultation meetings)(**a**).

New regulation 56E

11. Before regulation 57 (unpaid fees), insert—

"Fees payable in connection with regulatory advice meetings

56E.—(1) Unless regulation 56(3B)(a) applies, or regulation 17A(2)(a) of the Medical Devices (Northern Ireland Protocol) Regulations 2021(**b**) applies, the fee payable by a person with whom the Secretary of State holds a meeting in order to provide regulatory advice relating to a medical device is £987 for each hour that meeting takes.

(2) Any fee payable under this regulation must be paid within 14 days following written notice from the Secretary of State requiring payment of that fee.".

New regulation 58A

12. After regulation 58 (waivers, reductions and refunds), insert—

"Time for payment of fees - small companies

58A.—(1) Where a fee in regulation 56(1) is payable by a small company, if the small company so requests to the Secretary of State in writing, 50% of that fee shall be payable when the notice to which it relates is given to the Secretary of State and 50% of that fee shall be payable within six months of the date when the notice is given.

(2) For the purpose of this regulation, a company is a small company if, for the financial year before that in which the notice is given, the total value of products it has sold or supplied for the financial year is not more than the amount specified in item 1 in section 382(3) (qualification of company as small) of the Companies Act 2006(**c**) and either—

(a) the company's balance sheet total as defined in section 382(5) of the Companies Act 2006 is not more than the amount specified in item 2 in section 382(3) of that Act; or

(**a**) Inserted by S.I. 2023/377.
(**b**) S.I. 2021/905; relevant amending instruments are S.I. 2023/377 and 2024/221.
(**c**) 2006 c. 46. A relevant amendment was made by S.I. 2015/980.

(b) the average number of persons employed by the company in the financial year before that in which the notice is given (determined on a weekly basis) does not exceed the number specified in item 3 in section 382(3) of that Act.

(3) In this regulation, a reference to section 382 of the Companies Act 2006 is a reference to that section as amended by the Companies (Accounts and Reports) (Amendment and Transitional Provision) Regulations 2024(**a**).".

PART 3

Amendment of the Blood Safety and Quality Regulations 2005

Amendment of the Blood Safety and Quality Regulations 2005

13.—(1) Regulation 22 (fees) of the Blood Safety and Quality Regulations 2005(**b**) is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (b), for "£570" substitute "£621";

(b) in sub-paragraph (c), for "£509" substitute "£555".

(3) In paragraph (2A)(b), for "£967" substitute "£1,053".

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "£3,552" substitute "£5,324";

(b) in sub-paragraph (b), for "£1,776" substitute "£2,662".

(5) In paragraph (3A), for "£751" substitute "£818".

(6) In paragraph (3C)(c), for "£967" substitute "£1,053".

(7) In paragraph (5)—

(a) in sub-paragraph (a), for "£3,552" substitute "£5,324";

(b) in sub-paragraph (b), for "£1,776" substitute "£2,662".

(8) In paragraph (5B)—

(a) in sub-paragraph (a), for "£3,552" substitute "£5,324";

(b) in sub-paragraph (b), for "£1,776" substitute "£2,662".

(9) In paragraph (5C)—

(a) in sub-paragraph (a), for "£3,552" substitute "£5,324";

(b) in sub-paragraph (b), for "£1,776" substitute "£2,662".

(10) In paragraph (5E), for "£11,000" substitute "£11,974".

(**a**) S.I. 2024/1303.
(**b**) S.I. 2005/50; relevant amending instruments are S.I. 2005/2898, 2006/2013, 2008/525, 2010/554, and 2023/377.

PART 4

Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

14. The Medical Devices (Northern Ireland Protocol) Regulations 2021(**a**) are amended in accordance with regulations 14 to 22.

Amendment of regulation 7

15. In regulation 7(5) (registration of custom-made devices)(**b**), for "£240" substitute "£261".

Amendment of regulation 16

16. After regulation 16(4) (clinical investigation fees)(**c**), insert—

"(4A) Where the relevant fee is payable pursuant to paragraph (1)(a) by a small company, if the small company so requests to the Secretary of State in writing, 50% of that fee shall be payable when the application to which it relates is submitted to the Secretary of State and 50% of that fee shall be payable within six months of the date on which the application was submitted.

(4B) For the purpose of this regulation, a company is a small company if, for the financial year before that in which the application or notification is submitted or given, the total value of products it has sold or supplied for the financial year is not more than the amount specified in item 1 in section 382(3) (qualification of company as small) of the Companies Act 2006(**d**) and either—

(a) the company's balance sheet total as defined in section 382(5) of the Companies Act 2006 is not more than the amount specified in item 2 in section 382(3) of that Act; or

(b) the average number of persons employed by the company in the financial year before that in which the application or notice is submitted or given (determined on a weekly basis) does not exceed the number specified in item 3 in section 382(3) of that Act.

(4C) In this regulation, a reference to section 382 of the Companies Act 2006 is a reference to that section as amended by the Companies (Accounts and Reports) (Amendment and Transitional Provision) Regulations 2024(**e**).".

Amendment of regulation 17A

17. In regulation 17A(2) (advice in relation to intended clinical investigations)(**f**)—

(a) in sub-paragraph (a), for "£906" substitute "£987";

(b) in sub-paragraph (b), for "£782" substitute "£852".

(**a**) S.I. 2021/905; relevant amending instruments are S.I. 2023/377 and 2024/221.
(**b**) Amended by S.I. 2023/377.
(**c**) Amended by S.I. 2023/377.
(**d**) 2006 c. 46. A relevant amendment was made by S.I. 2015/980.
(**e**) S.I. 2024/1303.
(**f**) Inserted by S.I. 2023/377.

Amendment of regulation 19

18. In regulation 19 (fees payable in connection with the designation of notified bodies)(**a**)—

(a) in paragraph (3), for "£1,297" substitute "£1,503";

(b) in paragraph (6)—

(i) in sub-paragraph (b)(i), for "£631" substitute "£732";

(ii) in sub-paragraph (b)(ii), for "£171" substitute "£198".

Amendment of regulation 19C

19. In regulation 19C (fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device)(**b**)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£4,550" substitute "£4,953";

(ii) in sub-paragraph (b), for "£10,604" substitute "£11,543";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£900" substitute "£980";

(ii) in sub-paragraph (b), for "£2,451" substitute "£2,668";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£46,526" substitute "£50,644";

(ii) in sub-paragraph (b), for "£11,551" substitute "£12,574".

Omission of regulation 19D

20. Omit regulation 19D (fees for pre-consultation meetings)(**c**).

Amendment of Schedule 1

21.—(1) Schedule 1 (fees for clinical investigations)(**d**) is amended as follows.

(2) In Table 1 (clinical investigation of a class I device, class IIa device or class IIb device, which is neither an implantable device nor a long-term invasive device), in the second column (fee)—

(a) in entry 1, for "£7,472" substitute "£15,309";

(b) in entry 2, for "£5,711" substitute "£11,701";

(c) in entry 3, for "£207" substitute "£226".

(3) In Table 2 (clinical investigation of a class IIb device, which is either an implantable device or a long-term invasive device, or a class III device), in the second column (fee)—

(a) in entry 1, for "£15,627" substitute "£32,016";

(b) in entry 2, for "£11,069" substitute "£22,678";

(c) in entry 3, for "£331" substitute "£361".

(**a**) Amended by S.I. 2023/377 and 2024/221.
(**b**) Inserted by S.I. 2023/377.
(**c**) Inserted by S.I. 2023/377.
(**d**) Amended by S.I. 2023/377.

Amendment of Schedule 2

22.—(1) Schedule 2 (fees in connection with the designation of notified bodies)(**a**) is amended as follows.

(2) In Table 1 (application fees), in the second column (fee)—

(a) in entry 1, for "£35,672" substitute "£41,337";

(b) in entry 2, for "£8,918" substitute "£10,335";

(c) in entry 3, for "£35,672" substitute "£41,337";

(d) in entry 4, for "£12,571" substitute "£14,568";

(e) in entry 5, for "£18,212" substitute "£21,105".

(3) In Table 2 (fees for assessments and reviews), in the second column (fee)—

(a) in entry 1, for "£58,341" substitute "£67,606";

(b) in entry 2, for "£45,675" substitute "£52,929";

(c) in entry 3, for "£10,072" substitute "£11,672";

(d) in entry 4, for "£22,789" substitute "£26,408";

(e) in entry 5—

(i) in sub-paragraph (a), for "£18,583" substitute "£21,535";

(ii) in sub-paragraph (b), for "£22,789" substitute "£26,408".

Signed by the authority of the Secretary of State for Health and Social Care

Name
Minister of State
Date Department of Health and Social Care

We consent

Name
Name
Date Two of the Lords Commissioners of His Majesty's Treasury

(**a**) Amended by S.I. 2023/377 and 2024/221.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medical Devices Regulations 2002 ("the 2002 Regulations"), the Blood Safety and Quality Regulations 2005 ("the 2005 Regulations") and the Medical Devices (Northern Ireland Protocol) Regulations 2021 ("the 2021 Regulations").

The fee amounts in these Regulations represent increases in the majority of existing fees of between 9% and 16%, with some fees, primarily relating to clinical investigations, rising by more than this, and are set in line with a consultation document issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 29 August 2024. A summary of the consultation responses and the Government's response to the consultation are published on the MHRA's website (www.mhra.gov.uk).

Part 2 amends the 2002 Regulations. Regulations 3 and 4 increase existing fees payable to the Secretary of State in relation to the registration of devices. Regulations 5 to 7 increase existing fees payable to the Secretary of State in relation to the designation of approved bodies, UK notified bodies and conformity assessment bodies. Regulations 8 and 9 increase existing fees payable to the Secretary of State in relation to clinical investigation notices and consultations on the safety, quality and usefulness of a medicinal substance incorporated in a device. Regulation 11 introduces a new optional service provided by the Secretary of State, and corresponding fee, in relation to regulatory advice, and regulation 10 omits a fee replaced by the new service. Regulation 12 increases the time for payment by small companies of fees payable to the Secretary of State in relation to clinical investigations.

Part 3 amends the 2005 Regulations. Regulation 13 amends regulation 22 of the 2005 Regulations to increase the fees payable by blood establishments and hospital blood banks or facilities in relation to authorisation, operation and haemovigilance.

Part 4 amends the 2021 Regulations. Regulation 15 increases the existing fee in connection with the registration of custom-made devices. Regulation 16 increases the time for payment by small companies of fees payable to the Secretary of State in relation to clinical investigations. Regulations 17, 19 and 21 increase existing fees payable to the Secretary of State in connection with clinical investigations, advice in relation to intended clinical investigations and consultations on the safety, quality and usefulness of a medicinal substance incorporated in a device. Regulations 18 and 22 increase existing fees payable to the Secretary of State in connection with the designation of notified bodies. Regulation 20 omits a fee replaced by the new optional service provided by the Secretary of State in relation to regulatory advice introduced by regulation 11.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

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